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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,776	08/05/2003	Frederick G. St. Goar	37531-501C01 (17315-00200)	1704
78169 7590 12/09/2008 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, PC ATTN: PATENT INTAKE CUSTOMER NO. [EVALVE] ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 12/09/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,776	<b>Applicant(s)</b> ST. GOAR ET AL.	
	<b>Examiner</b> LINDSEY BACHMAN	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008 and 08 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8,10-12,14-18,43 and 51-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,10-12,14-18,43,51,52 and 54-66 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-25-08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This Office Action is in response to Applicant's amendment filed 8 August 2008.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed 8 August 2008 is sufficient to overcome the rejection of claims 1, 8, 10, 12, 14-18 and 62-65 based upon the rejection under 35 U.S.C. 103(a) under Oz in view of Keuhn as set forth in the last Office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1, 8, 11, 14-18, 62-66 are rejected under 35 U.S.C. 102(a) as being anticipated by Stevens et al. (US Patent 5,769,812).**

Claim 1, 14, 15, 18, 62: Stevens'812 discloses a device that contains a catheter (10) configured for advancement through a patient's vasculature; a stabilization structure (11) attached to the catheter that couples to a cardiac structure to reduce

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relative motion between the catheter and the cardiac structure (column 20, lines 50-59); and a supporting structure (73) releasably coupled to the catheter that is adapted for deployment directly on the annulus. The structure is movable between a delivery and expanded configuration (column 26, lines 51-56).

Claim 8, 11: The method contains a staple (76) for fastening the structure to the tissue.

Claim 16: The valve can be a mitral valve (column 20, lines 32-39).

ALTERNATE REJECTION: Claim 1, 63, 64, 66: Stevens'812 discloses a device that contains a catheter (77) configured for advancement through a patient's vasculature; a stabilization structure (76) removably attached to the catheter; and a supporting structure (72) releasably coupled to the catheter that is configured to be deployed directly on the annulus.

Claim 17: Stevens'812 further discloses a guide catheter (10).

Claim 65: The valve can be a mitral valve (column 20, lines 32-39).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 43, 51, 52, 54-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. (US Patent 5,571,215) in view of Northrup (US Patent 5,593,424).**

Claim 43, 54, 56, 62: Sterman'215 teaches that it is known to advance a catheter (22) through a patient's vasculature (column 10, lines 20-50) in which the catheter carries a plurality of anchors (column 10, lines 45-50). Sterman'215 further teaches performing work directly on the valve annulus of the heart but does not specifically teach the method of coupling a filament to the sutures and tightening the filament.

Northrup'424 teaches a method of modifying a heart valve (column 1, lines 8-12) that includes placing anchors (10) directly on the annulus (see Figures 2-4 and column 5, lines 17-48), coupling a filament to the anchors (column 5, line 59 to column 6, line 8) and tightening the filament to modify the annulus and reduce regurgitation (column 6, lines 3-8). It would have been obvious to one skilled in the art at the time the invention was made to perform the method taught by Northrup'424 percutaneously, as taught by Sterman'215 because it poses less risk to the health of the patient than a more invasive procedure.

Claim 51, 52: Northrup'424 teaches that the anchors contain a suture (column 5, line 17 to column 6, line 8).

Claim 55, 57, 58: Northrup'424 teaches that the method can be performed on a mitral valve (column 4, lines 34-46) and tightening the filament circumferentially tightens the annulus to reduce regurgitation in the mitral valve (column 5, lines 35-48).

Claim 59, 60 and 61: Northrup'424 teaches that tightening the filament comprises circumferentially tightening the filament by plicating portions of the annulus (column 5, lines 16-45).

#### ***Allowable Subject Matter***

Claim 53 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./  
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773